

REMARKS

Claims 1 – 8, 10 – 22, 24 – 28 and 30 -32 are pending in this application with claims 1 – 3 and 20 being withdrawn from consideration.

The Examiner notes the use of the trademarks BENADRYL and NEOSPORIN throughout the application and requests that each term be capitalized wherever it appears and be accompanied by the generic terminology. The paragraph beginning on page 10, line 3 of the specification was amended to capitalize the trademarks BENADRYL® and NEOSPORIN® and each trademark is accompanied by its generic equivalent. It is respectfully submitted that no new matter has been entered by this amendment and that the specification conforms to proper PTO policy and procedure.

Claim Objections

Claim 13 is objected to because line 4 recites “and effective amount” which is grammatically incorrect as it lacks an article, i.e. “an”. Claim 13 has been amended to insert the article “an” as suggested by the Examiner. Thus, it is respectfully submitted that this objection has been satisfied and should be withdrawn.

Rejection of Claims 4-8, 10 – 22, 24 – 28 and 30 - 32 under 35 U.S.C. 112, second paragraph

Claims 4-8, 10 – 22, 24 – 28 and 30 – 32 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner rejects claims 4 – 8, 10 – 22, 24 – 28 and 30 – 32 because the phrase “to relieve the itch pain, and swelling associated therewith” lacks antecedent basis. Claims 4, 5, 10, 13, 18, 21, 30 and 32 have been amended to state “to relieve any of itch, pain, and swelling associated therewith” thereby providing proper antecedent basis for the terms of the claim.

The Examiner further rejects claims 4 – 8, 10 – 22, 24 – 28 and 30 – 32 because the phrase “the site” lacks antecedent basis. Claims 4, 5, 10, 13, 18, 21, 30 and 32 have been amended to replace the rejected phase “the site” with “a site” thereby providing antecedent basis for all terms.

Claims 11, 19 and 31 we rejected as being indefinite for including the recitation of the trademarks Benadryl and Neosporin. Claims 11, 19, and 31 have been amended to replace the above trademarks with their generic equivalents. Support for this amendment can be found in the specification. In view of these amendments it is respectfully submitted that this rejection is satisfied and should be withdrawn.

Claims 11, 19, 31 are further rejected as they recite the term “such as” and are therefore indefinite. Claims 11, 19 and 31 have been amended in accordance with the suggestion of the Examiner to remove the term “such as”.

Claims 5, 10, 18 30 and 32 are rejected because they appear to be new independent claims. Applicant respectfully submits that the Examiner’s interpretation of claims 5, 18, 30 and 32 as new independent claims is correct and therefore, claims 5, 18, 30 and 32 have been amended to be in proper independent form.

In view of the above remarks, it is respectfully submitted that claims 4-8, 10 – 22, 24 – 28 and 30 – 32 particularly point out and distinctly claim the subject matter which applicant regards as the invention. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

**Rejection of Claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 under 35 U.S.C. 102(b)**

Claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 stand rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO/9937287).

The present invention recites a pharmaceutical composition for topical application to a site of insect bites and stings to relieve at least one of itch, pain, and swelling associated therewith. The composition consists of an effective amount of an abrasive ingredient and a carrier able to abrade the site and circulate at least one of a toxin and venom out from the site. The abrasive ingredient is selected from the group consisting of walnut shell, pumice, plastic material, sand, stone, glass, seed shell, fruit shell, seed, metal, chitosan and ground crab shell. The carrier is selected from the group consisting of vegetable oil, fruit oil, soap, surfactant, lubricant, mineral oil, petrolatum, gel, lotion, emollient, white petroleum, beeswax, di-propylene glycol, gum, lubricating jelly and olive oil.

Lee discloses a method for treating inflammatory symptoms such as burning, redness, itching and swelling and pain which accompany skin disorders other than wounds of the skin. The method includes topical application of a medicinal composition comprising a non-interlinked particulate bioactive glass mixed with a topical medicinal carrier to the side of the skin disorder. However, the composition as disclosed by Lee requires that the “particulate bioactive glass and the carrier are mixed before application to the skin.” (see Lee, page 5, lines 7 – 8). This is unlike the present claimed invention which is a prepared “composition consist[ing] of an effective amount of an abrasive

ingredient and a carrier". Furthermore, Lee states "if the two ingredients are mixed several days prior to application, e.g. one week, the ability of the composition to mitigate the inflammation may be comprised. This problem is particularly acute if the carrier causes bioactive glass to pre-react in a way that reduces the bioactivity of the glass." (see Lee, page 5, lines 8 – 12). Therefore, Lee clearly relies on a specific property of the glass, bioactivity, in order for the invention as disclosed therein to function properly. Lee defines bioactive glass as "glass material having an oxide of silicon as a major component and capable of bonding with growing tissue when reacted with physiological fluids" (see Lee, page 2, lines 17 – 19). Therefore, the bioactive glass of Lee is not analogous to the abrasive ingredient disclosed by the present claimed invention. While the abrasive ingredient of the present claimed invention includes glass, the function of the glass of the present claimed invention is to "abrade the site and circulate out at least one of a toxin and venom from said site". This circulation "relieves any of itch, pain and swelling" which results from an insect bite. The bioactive glass of Lee is a healing agent which biologically bonds with growing tissue and is thus wholly unlike the "abrasive ingredient" of the present claimed invention which is "able to abrade the site".

Furthermore, Lee merely discloses "optionally, with gentle massage, to work the composition into the skin" (see Lee, page 6, lines 5 – 7). Lee neither discloses nor suggests a pharmaceutical "composition consisting of an effective amount of an abrasive ingredient and a carrier able to abrade the site and circulate at least one of a toxin and venom out from said site" as in the present claimed invention.

Additionally, as stated in Lee on page 6, lines 3- 4, the composition disclosed by Lee is applied in a "treatment regimen...at the discretion of an attending medical practitioner". This is also unlike the present claimed invention which is selectively applied by any person who has been bitten or stung by an insect.

Also, Lee states on page 6, lines 1 – 2 that the composition is administered to a patient in a manner similar to that use for the administration of topical anti-inflammatory compositions now in clinical use. However, as discussed above, Lee neither discloses nor suggests an “abrasive ingredient and carrier able to abrade the site” as in the present claimed invention. Lee also neither discloses nor suggests to “circulate at least one of a toxin and venom out from said site” as in the present claimed invention. As a composition “able to abrade the site and circulate at least one of a toxin and venom out from said site” is contrary to the method of administering topical inflammatory compositions used by Lee, applicant respectfully submits that Lee does not anticipate the pharmaceutical composition of the present claimed invention.

In view of the above remarks and amendments to the claims, it is respectfully submitted that the present claimed invention is not anticipated by Lee. As independent claims 5, 10, 21 and 30 include limitations similar to claim 4, it is respectfully submitted that claims 5, 10, 21 and 30 are patentable for the same reasons as discussed above with respect to claim 4. As claim 6 is dependent on claim 5, claim 11 dependent is on claim 10, claims 22, 25 and 26 are dependent on claim 21 and claim 31 is dependent on claim 30, it is further respectfully submitted that claims 6, 11, 22, 25, 26 and 31 are patentable for the same reasons as discussed above with specific reference to claim 4. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

**Rejection of Claims 7, 8, 27 and 28 under 35 U.S.C. 103(a)**

Claims 7, 8, 27 and 28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO99/37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31.

The Examiner states that while Lee did not specifically teach the bioactive glass being formulated into an aqueous carrier, or as a paste, Lee states that the bioactive glass

and topical treatment can be combined in any pharmaceutically acceptable carrier to facilitate application to the skin. However, as discussed above, Lee neither discloses nor suggests a composition including "an abrasive ingredient and a carrier able to abrade the site" as in the present claimed invention. Furthermore, Lee neither discloses nor suggests to "circulate at least one of a toxin and venom out from said site" as in the present claimed invention.

In view of the above remarks and amendments to the claims, it is respectfully submitted Lee when applied to claims 4, 6, 10, 11, 21, 22, 25, 26; 30 and 31 adds nothing that would make the present invention as claimed in claims 7, 8, 27 and 28 unpatentable. As claims 7 and 8 are dependent on claim 5, and claims 27 and 28 are dependent in claim 21, it is respectfully submitted that claims 7, 8, 27 and 28 are patentable for the same reasons as discussed above with specific reference to claims 4, 5 and 21. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

**Rejection of Claims 5, 12 – 19 and 32 under 35 U.S.C. 103(a)**

Claims 5, 12 – 19 and 32 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO99/37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 and further in view of Rubin (US 5,543,149) for the reasons discussed in the Office Action.

Rubin discloses a method of treating insect bites with digestive enzymes such as papain and pancreatin. However, similarly to Lee, Rubin neither discloses nor suggests a composition including "an abrasive ingredient and a carrier able to abrade the site" as in the present claimed invention. Furthermore, Rubin neither discloses nor suggests to "circulate at least one of a toxin and venom out from said site" as in the present claimed invention. Additionally, Rubin specifically discloses a method for reducing the itch associated with

the bite of a blood feeding insect such as a mosquito or black fly. The pharmaceutical composition of the present claimed invention includes "an abrasive ingredient able to abrade the site and circulate at least one of a toxin and venom from said site" (of the insect bite). Therefore, the composition of Rubin is meant for treating a different ailment than the pharmaceutical composition of the present claimed invention.

In view of the above remarks and amendments to the claims, it is respectfully submitted Rubins adds nothing to Lee when applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 adds nothing that would make the present invention as claimed in claims 5 and 32 unpatentable. As claims 12 – 19 are dependent on claim 13 and claim 32 is dependent on claim 30, it is respectfully submitted that claims 12 – 19 and 32 are patentable for the same reasons as discussed above with specific reference to claims 4, 5 and 30. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

No additional fee is believed due with this response. However, should a fee be due please charge the fee to Deposit Account No. 502828.

Based upon the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawings, then it is respectfully asked that such changes be made by Examiner's amendment, if the Examiner feels this would facilitate passage of the case to issuance.

Alternatively, should the Examiner have any questions, comments, or feel that a personal discussion might be helpful in advancing this case to allowance and issuance, she is cordially invited to contact Mr. Jack J. Schwartz at 1350 Broadway, Suite 1507, New York, New York 10018, Tel. No. (212) 971-9017, so that the present application can receive

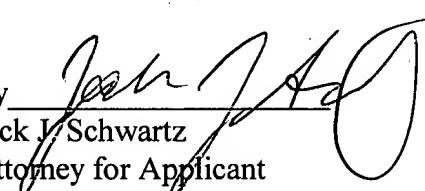
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an early notice of allowance. The address and telephone number for Jack J. Schwartz stated above is as listed on the original Power of Attorney.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,  
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